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10/589,674	04/03/2007	Markus Graf Matuschka-Greiffenclau	DEBE:068US/10609441	9938

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EXAMINER	
PYLA, PAUL D	
ART UNIT	PAPER NUMBER
1653	

NOTIFICATION DATE	DELIVERY MODE
03/29/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/589,674	MATUSCHKA-GREIFFENCLAU ET AL.	
	Examiner	Art Unit	
	PAUL D. PYLA	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-18* is/are pending in the application.

5a) Of the above claim(s) *1-17* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *18* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/8/2011 & 3/2/2012*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Please note that the Examiner for this application has changed.

Response to Amendments

Applicants' amendments filed 11/17/2011 to claim 18 have been entered. Claims 1-18 are pending, while claims 1-17 are withdrawn from further consideration as being directed to a non-elected invention. Claim 18 is being considered on its merits. References not included with this Office Action can be found in a prior Action. Any rejections of record not particularly addressed below are withdrawn in light of the claim amendments and Applicants' comments.

New Rejections

The following rejections were necessitated by Applicants amendments to the claims.

Claim Rejection - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 18 recites a "method of affecting ethanol metabolism in a human subject…administering to a subject the food composition…reduces ethanol…in the human subject." The claim is unclear whether "a subject" is different from the human

subject twice recited in the claim. Further, claim 18 lacks proper antecedent basis for "*the* food composition." Clarification is required.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicants are advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claim 18 is rejected under 35 U.S.C. § 103(a) as obvious over Naito (EP 0652012; 1995), taken in view of Terajima et al., JP H4-342528 (1992; cited as Foreign Patent Document B9 in the IDS date 7/8/2011), Miasnikov et al. (U.S. PGPUB 2002/0006910; 2002; cited as U.S. Patent Document A1 in the IDS date 5/31/2007),

and Mansouri et al., The Journal of Pharmacology and Therapeutics, Vol. 298, No.2, pp. 737-743 (2001; previously cited NPL document U, PTO-892 form dated 8/12/2011).

Naito teaches a composition used to treat drunkenness (i.e., alcohol intoxication via ethanol metabolism) that comprises D(+) glucose (i.e. dextrose) and the amino acids cysteine and glutamine (Abstract, column 5, lines 10-28, column 6, lines 15-50). Naito teaches that the composition can have 0.2-6.0 grams of glucose (dextrose) and 10-3000 mg of amino acids (column 5, lines 10-28),

Although Naito teaches that the above composition can be combined with vitamins B and C (Abstract), Naito does not teach the use (and amounts) of these vitamins in a composition to treat alcohol intoxication (ethanol metabolism).

Further, Naito does not teach administering riboflavin, succinic acid and/or fumaric acid and coenzyme Q_{10} within a composition that affects ethanol metabolism (i.e., alcohol intoxication).

Terajima teaches a composition for the promotion of alcohol and acetaldehyde metabolism that comprises vitamin B2 (riboflavin) and vitamin B6 as the active components, where the composition shows a strong effect of alcohol and acetaldehyde metabolism (Abstract). Terajima also teaches that including vitamin C, cysteine or vitamin B1 provides further improved effects (Abstract). Terajima teaches a method of administering the composition to a subject where a dose of the composition (e.g., vitamin B2 (5-100 mg), vitamin B6 (10-100 mg), vitamin C(200-500 mg), cysteine (50-500 mg) and vitamin B1 (5-200 mg)) is administered one to several times before or after drinking an alcoholic drink (Abstract).

Miasnikov teaches a medicine that can be used both in the foodstuffs industry, in the form of a biologically active additive to food, and in the pharmacological industry for solving the problem of lessening the severity of drunkenness, for removing alcohol intoxication and hangover, and also for lessening attraction to alcohol (i.e., affecting ethanol metabolism; paragraph 2). Miasnikov also teaches of providing a means for allaying drunkenness, preventing and removing alcohol intoxication and the hangover syndrome (i.e., affecting alcohol metabolism), in the form of a biologically active food additive composition that comprises (as active substances per 1000 mg of the composition) succinic acid (10 to 400 mg), L-glutamic acid (10 to 400 mg), at least one component based on fumaric acid (2 to 300 mg), ascorbic acid (vitamin C; 1-300 mg) and glucose (dextrose) and at least one energizer such as amino acids (remainder to 1000 mg composition; paragraph 13). Miasnikov also teaches that the composition actively lowers the concentration of ethanol and acetaldehyde in the subject (paragraph 19). Further Miasnikov teaches that succinates are adaptogens, specific antidotes for acetaldehyde; they are also mitochondrial antioxidants, detoxicants, anti-ischemic and anti-hypoxic agents, anti-mutagens and effective energizers (paragraph 20). Miasnikov also teaches that fumarates, together with succinates, ensure membrane stability, stabilize the blood circulation system, and provides a powerful, time-extended antihypoxic effect (paragraph 21). Additionally, Miasnikov teaches that vitamin C is an active water-soluble antioxidant, an activator of the adrenal cortex, which provides an anti-stress effect of the composition (paragraph 24). Miasnikov further teaches a method for allaying drunkenness, for preventing and removing alcohol intoxication and

the hangover syndrome by administering the medicinal composition as described above (claims 12-19).

Mansouri teaches that ethanol metabolism causes oxidative stress and lipid peroxidation not only in liver but also in extra-hepatic tissues (Abstract). Mansouri also teaches that reactive oxygen species (ROS) and free radicals are generated during ethanol metabolism, causing oxidative stress and lipid peroxidation in liver (and other tissue; page 737, column 1 paragraph 1). In hepatocytes, ethanol-induced free radical and ROS generation involves mitochondria and microsomal cytochrome P450 2E1 (page 737, column 1 paragraph 2). Mitochondria are major targets for ethanol toxicity in liver (and other tissues), where in the liver, acute and chronic ethanol intoxication causes oxidative damage to mitochondrial proteins, phospholipids and mitochondrial DNA (page 737, column 1, paragraph 2 to column 2, paragraph 1). Mansouri teaches a method of affecting ethanol metabolism by administering coenzyme Q_{10} daily (45 mg/kg), which exerted protective effects against ethanol-induced mitochondrial DNA depletion and degradation in liver (Table 2, and page 738, column 1, paragraph 3). Mansouri also teaches that preventive treatments are needed since some alcohol abusers keep drinking despite all recommendations and warnings and that coenzyme Q_{10} (Table 2), or vitamin E and melatonin (Fig. 3) all exerted protective effects against ethanol-mediated hepatic mitochondrial DNA depletion and damage (page 742, column 1, paragraph 2).

A person of ordinary skill in the art would have had a reasonable expectation of success in combining Naito, Terajima, Miasnikov and Mansouri since the references all

teach dietary or supplement compositions for the treatment of alcohol related symptoms from alcohol metabolism in a subject. The skilled artisan would have been motivated to combine the reference since each reference provides compositions that are both known to be useful for treating alcohol induced disorders and administered to substantially identical subject populations. The combination of multiple products (i.e. compositions that ameliorate alcohol intoxication by affecting ethanol metabolization) each known to have the same effect to produce a final product having the same effect is *prima facie* obvious. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See MPEP § 2144.06.

Additionally, it is also noted that instant claim 18 is directed towards a method of administering a composition comprising dextrose, vitamin C, L-glutamine, cysteine, riboflavin, succinic acid and/or fumaric acid and coenzyme Q_{10} to a subject. The transitional term "comprising" does not exclude additional, unrecited elements or method steps (see MPEP § 2111.03).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the references to arrive at a composition comprising dextrose (glucose), vitamin C, L-glutamine, cysteine, riboflavin, succinic acid and/or fumaric acid and coenzyme Q_{10}. It also would have been obvious to treat a

subject with alcoholic intoxication (i.e., affected by ethanol metabolization) by administering such a composition.

With regard to the specific amounts of each component present in amended claim 18, the above references individually overlap the ranges for L-glutamine, cysteine, riboflavin, succinic acid and fumaric acid. In combination, the references teach a vitamin C level that would fall within the recited range. Coenzyme Q_{10} is dosed at 45 mpk, which is greater than what Applicants claim. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). See MPEP § 2144.05 (II)(A).

In the alternative, the compositional amounts that are at or near the recited ranges would be results effective variables. The administering of a composition of the above components would be based on common sense on the part of the artisan of ordinary skill where the amounts of dextrose (glucose) and coenzyme Q_{10} would be based on varying the concentration amounts within the composition to further enhance an ethanol metabolizing affect within a subject. A holding of obviousness over the cited

claim is therefore clearly required. Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Response to arguments

With regard to Applicants' arguments regarding picking and choosing from references that rely on impermissible hindsight (Reply, page 8) in view of the new rejection, the prior art (Naito, Terajima, Miasnikov and Mansouri) discussed above are directed towards treating alcohol-related side effects of ethanol metabolism. Therefore, combining their teachings together and administering the composition to the same subject population would have been obvious to a person having ordinary skill in the art, since there is a reasonable expectation of success in treating such a condition.

Further as indicated above, instant claim 18 is directed towards a method of administering a composition comprising dextrose, vitamin C, L-glutamine, cysteine, riboflavin, succinic acid and/or fumaric acid and coenzyme Q_{10} to a subject. The transitional term "comprising" does not exclude additional, unrecited elements or method steps (see MPEP § 2111.03).

Additionally, Applicants argue that in light of the specific amounts now recited in the claims that it would be virtually impossible to arrive at the specified amounts of each claimed component from the cited references in the previous rejection (which have been withdrawn). It appears that Applicants are arguing that a combination of references with a certain amount of components would not have been "obvious to try" to one of ordinary skill in the art (at the time of filing the application) and that the examiner was "picking

and choosing only those elements from the claims from the hundreds (if not thousands) of possible agents." (Reply, page 8).

Although this rationale was not used above, it is noted that an "obvious to try" rationale may support a conclusion that a claim would have been obvious where one skilled in the art is choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success. "[A] person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1397 (2007). See MPEP § 2145.

In this case, the new rejection based on Naito, Terajima, Miasnikov and Mansouri has a finite number of identified components (some of which overlap in the references), where the references provide predictable solutions (affect ethanol metabolism), with a reasonable expectation of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, *e.g.*, *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. §§ 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

Claim 18 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of co-pending Application No. 11/997,127. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instantly claimed invention is directed a method of affecting ethanol metabolism in a human subject, where a food composition or dietary supplementation (comprising dextrose at 7.2 to 12.8 g, vitamin C at 0.78 to 1.18 g, L-glutamine at 1.23 to

1.7 g, cysteine at 460 to 540 mg, riboflavin at 32 to 48 mg, succinic acid at 90 to 110 mg, and/or fumaric acid at 90 to 110 mg, and coenzyme Q10 at 50 to 70 mg) is administered to a subject, wherein the method reduces ethanol and acetaldehyde in the human subject.

Co-pending Application No. 11/997,127 teaches a method of treating a disease or condition (conditions including hangover syndrome, flushing syndrome, alcohol-induced headache and/or alcoholic intoxication) that comprises administering to a subject suffering from or at risk of one of the foregoing diseases or conditions a composition dose (comprising: Niacin at 1 to 20 mg, dextrose at 7.2 to 12.8g, vitamin C at 0.78 to 1.18g, L-glutamine at 1.23 to 1.7g and/or L-glutamic acid at 1.23 to 1.7g, cysteine at 460 to 540 mg, riboflavin at 32 to 48 mg, succinic acid at 90 to 110 mg, fumaric acid at 90 to 110 mg and coenzyme Q10 at 50 to 70 mg), wherein the composition reduces blood alcohol content and/or blood acetaldehyde content.

It is noted that instant claim 18 does not require niacin within its composition as in co-pending Application No. 11/997,127 claim 12. However, it is also noted that instant claim 18 recites the transitional phrase “comprising,” which does not exclude additional, unrecited elements (such as niacin) or method steps (see MPEP § 2111.03). Accordingly, the scope of the instant application is fully enclosed within the scope of co-pending Application No. 11/997,127. Therefore, the instantly claimed method encompasses and/or is encompassed by method claims 12 of co-pending Application No. 11/997,127.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed. No claims are free of the art.

Applicants' Amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to PAUL D. PYLA whose telephone number is (571) 270-1689. The Examiner can normally be reached Monday-Friday between the hours of 8:00 AM to 4:30 PM, Eastern Time.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Sue Liu, can be reached at (571) 272-5539. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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/Paul D. Pyla/

Examiner, Art Unit 1653

/SUE LIU/

Supervisory Patent Examiner, Art Unit 1653